PATENT
OSTEONICS 3.0-094 DIV

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of TUNC	:	
	:	Group Art Unit: 3731
Application No.	:	
	:	Examiner: D. Reip
Filed: Herewith	:	
	:	Date: January 8, 2001
For: BIOABSORBABLE MATERIALS AND MEDICAL DEVICES MADE THEREFROM	:	

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Please enter the following amendment prior to an action on the merits.

IN THE SPECIFICATION:

Page 1, before "Field of the Invention" insert:

-- CROSS REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. Serial Number 09/263,268 filed March 5, 1999. --

IN THE CLAIMS:

Please cancel claims 1-33.

EXPRESS MAIL LABEL NUMBER: EL 479140135US

Please add new claims 34-66 as follows:

-- 34. (New) A material comprising a terpolymer having repeating units of L-lactide, D-lactide and glycolide.

35. (New) The material as set forth in claim 34 comprising at least about 2 molar percent D-lactide.

36. (New) The material as set forth in claim 35 comprising at least about 4 molar percent D-lactide.

37. (New) The material as set forth in claim 36 comprising about 2 to about 10 molar percent D-lactide.

38. (New) The material as set forth in claim 37 comprising about 80-90 molar percent L-lactide, about 2-10 molar percent D-lactide, and about 5-15 molar percent glycolide.

39. (New) The material as set forth in claim 38 comprising about 83-87 molar percent L-lactide, about 3-7 percent D-lactide, and about 8-12 molar percent glycolide.

40. (New) The material as set forth in claim 39 consisting essentially of 85 molar percent L-lactide, 5 molar percent D-lactide, and 10 molar percent glycolide.

41. (New) The material as set forth in claim 34 further comprising about 0.1-5 molar percent of a polymer formed from alpha-hydroxy-alpha-ethylbutyric acid; alpha-hydroxy-beta-methylvaleric acid; alpha-hydroxyacetic acid; alpha-hydroxybutyric acid; alpha-hydroxycaproic acid; alpha-hydroxydecanoic acid; alpha-hydroxyheptanoic acid; alpha-hydroxyisobutyric acid; alpha-hydroxyisocaproic acid; alpha-hydroxyisovaleric acid; alpha-hydroxymyristic acid; alpha-hydroxyoctanoic acid; alpha-hydroxystearic acid; alpha-hydroxyvaleric acid; beta-butyrolactone; beta-propiolactide; gamma-butyrolactone; pivalolactone; or tetramethylglycolide; or combinations thereof.

42. (New) The material as set forth in claim 34 made by the process comprising:

a) combining L-lactic acid monomer, glycolic acid monomer and at least about 2 molar percent D-lactic acid monomer to form a mixture; and

b) polymerizing substantially all of the mixture.

43. (New) The process of claim 42 wherein the polymerization is performed in the presence of a catalyst.

44. (New) The process of claim 43 wherein the polymerization is performed for between 24 and 72 hours.

45. (New) The material as set forth in claim 34 wherein the polymer has a heat of fusion of about 0.4-10 J/G, tensile strength retention at 52 weeks of incubation of at most about 25%.

46. (New) The material as set forth in claim 34 wherein the polymer has a tensile strength at 0 weeks of incubation in buffered saline at 37°C of about 65-101 MPa, tensile strength at 26 weeks of incubation of about 50-75 MPa, and tensile strength at 52 weeks of incubation of 0 MPa.

47. (New) The medical device as set forth in claim 34 wherein the polymer has a bending strength of at least 120 MPa at 0 weeks incubation in buffered saline at 37°C, at least 110 at 4 weeks incubation, at least 110 at 8 weeks incubation, at least 70 at 12 weeks incubation and at least 45 at 26 weeks incubation.

48. (New) The material of claim 34 having a heat of fusion of about 0.4-10 J/G.

49. (New) The material of claim 48 having a heat of fusion of about 0.5-5 J/G.

50. (New) The material of claim 49 formed from a resin having a heat of fusion of about 15-25 J/G.

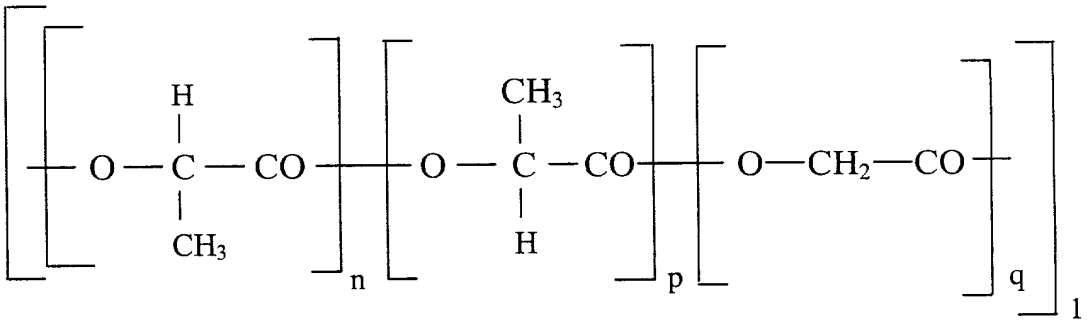
51. (New) The material of claim 50 formed from a resin having a heat of fusion of about 18-21 J/G.

52. (New) The material of claim 51 having tensile strength at 0 weeks of incubation in buffered saline at 37°C of about 74-92 MPa, tensile strength at 26 weeks of incubation of about 56-69 MPa, and tensile strength at 52 weeks incubation of about 0 MPa.

53. (New) The medical device as set forth in claim 34 wherein the polymer has an inherent viscosity between about 4.0 and 7.5 dl/g.

54. (New) The medical device as set forth in claim 53 wherein the polymer has an inherent viscosity of between about 6.0 and 6.5 dl/g.

55. (New) A material comprising a polymer having repeating units depicted by the formula:



where the molar percentages of the repeating units are:

$80 \leq n \leq 90$

$2 \leq p \leq 10$

$5 \leq q \leq 15$.

56. (New) The medical devices as set forth in claim 55 wherein the polymer further comprises about 0.1-5 molar percent of a polymer formed from alpha-hydroxy-alpha-ethylbutyric acid; alpha-hydroxy-beta-methylvaleric acid; alpha-hydroxyacetic acid; alpha-hyrdoxybutyric acid; alpha-hydroxycaproic acid; alpha-hydroxydecanoic acid; alpha-hydroxyheptanoic acid; alpha-hydroxyisobutyric acid; alpha-hydroxyisocaproic acid; alpha-hydroxyisovaleric acid; alpha-hydroxymyristic acid; alpha-hydroxyocantoic acid; alpha-hydroxystearic acid; alpha-hydroxyvaleric acid; beta-butyrolactone; beta-propiolactide; gamma-butyrolactone; pivalolactone or tetramethylglycolide; or combinations thereof.

57. (New) The medical device as set forth in claim 55 comprising at least about 4 molar percent D-lactide.

58. (New) The medical device as set forth in claim 55 comprising about 83-87 molar percent L-lactide, about 3-7 percent D-lactide, and about 8-12 molar percent glycolide.

59. (New) The medical device as set forth in claim 58 consisting essentially of 85 molar percent L-lactide, 5 molar percent D-lactide, and 10 molar percent glycolide.

60. (New) The medical device as set forth in claim 55 wherein the polymer has a tensile strength at 0 weeks of incubation in buffered saline at 37°C of about 65-101 MPa, tensile strength at 26 weeks of incubation of about 50-75 MPa and tensile strength at 52 weeks of incubation at 0 MPa.

61. (New) The medical device as set forth in claim 55 wherein the polymer has a bending strength of at least 120 MPa at 0 weeks incubation in buffered saline at 37°C, at least 110 at 4 weeks, at least 110 at 8 weeks, at least 70 at 12 weeks and at least 45 at 26 weeks incubation.

62. (New) The material of claim 55 having a heat fusion of about 0.4-10 J/G.

63. (New) The material of claim 55 having a heat fusion of about 0.5-5 J/G.

64. (New) The material of claim 55 formed from a resin having a heat of fusion of about 15-25 J/G.

65. (New) The material of claim 55 formed from a resin having a heat of fusion of about 18-21 J/G.

66. (New) The medical device as set forth in claim 55 wherein the polymer has an inherent viscosity between about 4.0 and 7.5 dl/g. --

REMARKS

Entry of the foregoing amendments prior to an action on the merits is requested. No new matter has been added.

The claims herein are directed to the non-election claims of Group I of the claims set forth in the restriction requirement issued by the Examiner on May 2, 2000 in the parent application, U.S. Serial No. 09/263,268.

It is believed that the bioabsorbable materials and medical devices made therefrom of the present invention is patentably distinguishable over the prior art. Accordingly, entry of the foregoing amendments and passage of the application to issue are earnestly solicited.

If there are any fees due and owing in connection with this requested amendment, the Examiner is authorized to charge applicant's Deposit Account No.: 12-1095.

Respectfully submitted,

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP

RAYMOND W. AUGUSTIN
Reg. No. 28,588

600 South Avenue West
Westfield, New Jersey 07090
Telephone: (908) 654-5000
Facsimile: (908) 654-7866
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